Policy Statement 6.12 – Custom-made Dental Devices

Position Summary

The construction of Custom-Made Dental Devices must comply with the applicable Australian and international regulations and standards.

1. Introduction

1.1. The fitting and intra-oral adjustment of custom- made dental devices is part of the practice of dentistry.

1.2. Australian dental laboratories are regulated by the business constraints of Commonwealth, state and local government legislation. These regulations address occupational health and safety, infection control, quality of materials used and waste management.

1.3. Some Australian dental laboratories and dentists source custom-made dental devices from overseas. The regulations that apply to Australian dental laboratories may not apply to overseas laboratories.

1.4. Some custom-made dental devices can only be sourced from overseas.

1.5. The quality and safety of custom- made dental devices are more relevant than the site of manufacture.

1.6. Australian Governments support free-trade agreements and universal application of competition policy.

1.7. The Therapeutic Goods Administration (TGA) regulates the standards of dental materials, instruments and equipment, mostly recognising standards of the International Organization for Standardization (ISO).

1.8. Digital impressions and 'onsite' fabrication of custom-made dental devices in dental practices are becoming more common.

Definitions

1.9. DENTAL PRACTITIONER is a person registered by the Board to provide dental care.

1.10. CUSTOM MADE DENTAL DEVICE is 'a device made at the request of a health professional specifying its design characteristics or construction; intended for a particular individual.

2. Position

2.1. Dental practitioners have a responsibility to be aware that all materials used in custom- made dental devices should comply with the current version of with Therapeutics Goods (Medical Devices) Regulations 2002.

2.2. Dental laboratories and suppliers of custom-made dental devices have a responsibility to ensure and guarantee that laboratory work complies with TGR 2002 and confirm this to the dental practitioner.

2.3. All materials used in custom-made dental devices, wherever sourced, must comply with ISO standards.

Policy Statement 6.12

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